

Attorney Docket No.: F7590(V)
Serial No.: 10/072,570
Filed: February 8, 2002
Confirmation No.: 1952

BRIEF FOR APPELLANT

Sir:

This is a Brief on appellant's Appeal from the Examiner's Final Rejection in an Office Action mailed November 25, 2008 concerning the above-identified application.

The Commissioner is hereby authorized to charge any additional fees, which may be required to our deposit account No. 12-1155, including all required fees under: 37 C.F.R. §1.16; 37 C.F.R. §1.17; 37 C.F.R. §1.18.; 37 C.F.R. §1.136.

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BRIEF FOR APPELLANT

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I. REAL PARTY IN INTEREST

Unilever Bestfoods, North America, Division of Conopco, Inc., a corporation of New York is the real party in interest.

II. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals or interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

III. STATUS OF CLAIMS

Claims 11-16, 19-24 and 27-29 stand rejected in a Final Office Action mailed November 25, 2008.

Claims 1-9 have been withdrawn

No claims have been allowed.

Claims 10, 17, 18, 25 and 26 have been cancelled.

Claims 11-16, 19-24 and 27-29 are on Appeal.

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IV. STATUS OF AMENDMENTS

No claims were amended subsequent to the Final Office Action mailed November 25, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 19 concerns a food product selected from the group consisting of a margarine, a dressing, a sweet, a cereal bar, a breakfast cereal and a beverage (original claim 18, page 9, lines 18-23) that includes an extract of a fermentation product (page 19, lines 1-4) formed by fermenting a substrate comprising more than 50% by weight of soy ingredients (original claim 2) with a statins producing *monascus ruber* fungus (page 17, lines 11-13). The fermentation product comprises one or more statins (page 1, lines 1-2) and one or more polyphenols (page 4, lines 26-28) and has a Hue a^* value less than 20 (page 4, lines 20-30). The soy ingredients are selected from the group consisting of whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes (page 16, line 23 to page 17, line 9). The extract is an ethanol extract or an edible oil extract (page 19, lines 4-7).

Claim 11 specifies that the amount of the one or more statins recited in claim 19 is 5-500 mg/kg (page 10, lines 8-9).

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Claim 12 specifies that the amount of genistein recited in claim 21 is 20-95 wt% of the sum of the amounts of genistein and genistin (page 11, lines 18-20).

Claim 13 specifies that the amount of genistein recited in claim 21 is 20-80 wt.% of the sum of the amounts of genistein and genistin (page 11, line 19).

Claim 14 specifies that the amount of statins recited in claim 19 is 5-500 mg/kg (page 10, lines 8-9) and the amount of polyphenols recited in claim 19 is 1 wt.% or higher (page 5, lines 1-3).

Claim 15 specifies that the amount of polyphenols recited in claim 14 is 5 wt.% or higher (page 5, lines 2-3).

Claim 16. specifies that the fermentation product specified in claim 19 has a Hue a^* value less than 10 (page 4, lines 29-30).

Claim 20 specifies that the substrate recited in claim 19 comprises more than 80% soy ingredients (original claim 2 and page 22, line 7).

Claim 21 specifies that the polyphenols recited in claim 19 comprise genistein and genistin, and wherein the amount of genistein is 10-99 wt.% of the sum of the amounts of genistein and genistin (page 11, lines 15-20).

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Claim 22 specifies that the fermentation product recited in claim 19 is formed by fermenting a substrate comprising more than 50% of soy ingredients with statins producing fungus in the presence of more than 10% of a vegetable oil (page 20, lines 4-6).

Claim 23 specifies that the fermentation product recited in claim 19 further comprises an amount of one or more compounds selected from the group consisting of polyunsaturated fatty acids, phytosterols, proteins, peptides, dietary fibers, and saponins (page 5, lines 11-14).

Claim 24 specifies that the substrate recited in claim 19 comprises whole soybeans or crushed whole soybeans (page 16, lines 23-31).

Claim 27 specifies that the Hue a* value recited in claim 19 is less than 0 (page 4, line 30).

Claim 28 specifies that the edible oil recited in claim 19 is a vegetable oil (page 19, lines 5-6).

Claim 29 specifies that the monascus ruber fungus recited in claim 19 is monascus ruber strain F125 or monascus ruber strain F125 M1-4 (page 17, lines 11-18).

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VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Are claims 11-16, 19-21, 23, 24, 27 and 29 unpatentable under 35 USC §103(a) over Manzoni et al (Production of Statins by filamentous Fungi, 1999), Zhang et al (US 6,046,022) and Chaihorsky (US 5,670,632)?

Are claim 22 and 28 unpatentable under 35 USC §103(a) over Manzoni et al (Production of Statins by filamentous Fungi, 1999), Zhang et al (US 6,046,022) Chaihorsky (US5,670,632) in further view of Zilliken (US 4, 218,489)?

VII. APPELLANT'S ARGUMENTS

Are claims 11-16, 19-21, 23, 24, 27 and 29 unpatentable under 35 USC §103(a) over Manzoni et al (Production of Statins by filamentous Fungi, 1999), Zhang et al (US 6,046,022) and Chaihorsky (US 5,670,632)?

Relevant Facts

Manzoni et al screened 14 strains of *Monascus* and 7 strains of *Aspergillus* for the production of lovastatin, pravastatin, mevastatin and monacolin (Abstract and p.254, left column, 3rd paragraph).

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The growth medium employed by Manzoni et al contained 3% whole or defatted soybean flower (p 254 left column 4th paragraph). All extracts were carried out with ethyl acetate (p. 254, left column, last paragraph). Manzoni et al are silent regarding the color of any extract.

Manzoni et al reported that among *Monascus* strains only *Monascus paxii*, not *Monascus ruber*, had notable activity for the production of all statins. For example, only *M. paxii* strain AM12M isolated as a spontaneous mutant showed good lovastatin yield (p.255 left column next to last paragraph); *M. paxii* was the only monascus strain that produced pravastatin (p.255, right column, 1st paragraph), and *M. paxii* gave the highest yield for monacolin J (p.255, right column, 1st paragraph).

Manzoni et al found that *Aspergillus terreus* in contrast to all the *Monascus* species produced much higher yields of statins. The overall conclusions reached by Manzoni et al (page 255, column 2, next to last paragraph) was "From all the results of these preliminary screening experiments it can be concluded that lovastatin and pravastatin can be produced in appreciable yields by *Aspergillus terreus* strains employing the defatted soybean flower medium." [emphasis added]

Zhang et al discloses methods and compositions "which comprise red rice fermentation products, that can be used as natural dietary supplements and/or medicaments for the treatment or prevention of hyperlipidemia and associated

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disorders and symptoms, such as cardiovascular diseases". (Abstract - emphasis added)

Zhang et al teaches that "Red rice is the fermentation product of one or a mixture of Monascus fungi, comprising chiefly Monascus purpureus Went, and in lesser proportions other Monascus species, e.g., Monascus ruber van Tieghem, Monascus Fuliginosus Sato, Monascus Pilosus Sato and Monascus albidus Sato". (column 4, lines 61-65).

Zhang et al further discloses that "For all of the media preparations rice or another grain is used as a carbon source." column 7, lines 4-5 – emphasis added. Zhang teaches that "the source of nitrogen is selected from the group consisting of beans (e.g. soya bean powder, pressed soybean cake), or peanut powder (or pressed peanut cake), peptone, rice extract powder, thick beef juice, silkworm chrysalis powder, or inorganic salts (e.g. NH_4NO_3 , etc.)" (Column 7, lines 15-20).

All of the exemplary culture media disclosed by Zhang et al, in Example 1 contain rice at a level of about 55 to 65%. The media disclosed in Examples 1(B)-(F) contained powdered soy beans as the nitrogen source at a level of about 5-6.5% (Percentages calculated from the data provided in the examples)

Chaihorsky was relied upon by the Examiner for its teaching that "isoflavones have been isolated from soybean plants for use as dietary supplements and include isoflavones in a glucone form such as genistein and genestin" and that "typically the

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isoflavones are eluted by polar solvents such as methanol or ethanol". [Office Action mailed November 25, 2008 - emphasis added].

Chaihorsky is in fact silent about extractions of any fermentation products of soy. Chaihorsky teaches the use of ethanol as an eluent in a chromatographic separation of the products of soybean plant extracts (i.e., not fermentation products), principally 7-glycosyl-isoflavones, i.e., glycosylated isoflavones (claim 1 and column 2, line 40). The solvent used in the soy plant extraction taught by Chaihorsky is in fact an aqueous alkali solution (column 1, lines 32-34).

The key soy plant-extract separated by chromatography according to Chaihorsky is 7-glycosyl-isoflavones (claim 1 and column 2, line 40).

Finally, Manzoni et al, Zhang et al and Chaihorsky are all silent regarding soy fermentation extracts which are substantially uncolored as measured by having a Hue a^* value less than 20.

In contrast, appellants' invention is directed to margarine, dressing, sweets, cereal bar, breakfast cereal or beverage which includes an ethanol or edible oil extract of a fermentation product of *Monascus ruber* fungus. The fermentation product is produced under conditions which yields a low color as measured by a Hue a^* value less than 20. The fermentation substrate includes at least 50% whole soybeans, crushed whole soybeans, soy protein, soy milk or soy flakes.

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Applicants discovered that the fermentation of soy ingredients (e.g., crushed soybeans) with *Monascus ruber* contained a collection of beneficial "soy actives" (page 8, lines 15-17) but in contrast to prior art fermentation products of other monascus strains and substrates (e.g., rice as the substrate fermented with *Monascus purpureus* *went*), applicants' fermentation product had a low color which allowed the "soy actives" to be easily extracted with ethanol or vegetable oil, and incorporated directly in a variety of foods without affecting their normal color. Thus, applicants found a practical way to incorporate a collection of natural and beneficial ingredients in foods without the expense of adding highly purified individual components.

Principles of Law

"In proceedings before the Patent and Trademark office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art." *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992).

"In determining whether obviousness is established by combining the teachings of the prior art, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re GPAC Inc.*, 57 F.3d 1573, 1581 (Fed. Cir. 1995) (internal quotations omitted).

In this regard "On the issue of obviousness the combined teachings of the prior art as a whole must be considered". "It is impermissible within the framework of 103 to pick and choose from any one reference only so much of it as will support a given

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position, to the exclusion of other parts necessary to the full appreciation of what such references fairly suggest to one of ordinary skill in the art" (EWP Corp v. Reliance Universal, Inc 755 F.2d at 907 – see also Bausch & Lomb, Inc v. Barnes-Hind/Hydracurve, Inc 796 F.2d 44, 448-49 (Fed Cir. 1986).

Appellants' Arguments

Appellants have argued that their invention is not rendered obvious by the combination of Manzoni et al, Zhang et al and Chaihorsky because the combination of references taken as a whole would not have suggested to a person of ordinary skill in the art the combination of elements recited in appellants' claimed invention taken as a whole nor would the references have provided a reasonable expectation of success, nor would they have provided all the claim limitations recited in appellants' claims as required for obviousness under 103(b).

Appellants' arguments and the reasons appellants believe the Examiner is in error are discussed below.

Regarding claim 19

As discussed above under the Facts section, Manzoni et al essentially teaches that *M. ruber* is unremarkable in its ability to produce statins. There is no evidence in Manzoni et al to suggest that *M. ruber* produced any level of statins from the results presented in the reference.

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In fact, appellants submit that that a person of ordinary skill in the art having read Manzoni et al would have reasonably been dissuaded from selecting any *Monascus* strain, other than the specialized strain AM12M of *M. paxii*, since this strain was the only *Monascus* fungus which produced all the key statins in appreciable quantities. Appellants' submit that the artisan would have been led to select *Aspergillus* because Manzoni et al specifically teach that *A. terreus* provided much higher yields than even the best *Monascus* strain, which is the specialized AM12M *M. paxii*.

Furthermore, there is no teaching or suggestion in Manzoni et al about using more than 50% by weight of soy ingredients (e.g., crushed whole soybeans) as the fermentation medium, a level over 16 times higher than that taught by Manzoni et al. Furthermore, in some cases whole soy flower was inferior to defatted soy flower.

Zhang et al was joined to Manzoni et al by the Examiner "to provide motivation for formulation of a food product" (Final Rejection, page 6)

Appellants are aware of the use of fermented rice, "red rice", as a traditional Chinese medicine (page 2, lines 26-30) and as a food supplement (page 3, lines 8-11). However, as appellants have noted on page 3, line 25 to page 4, line 2 of their disclosure, this material is highly colored and is of limited use in the production of many food products because of discoloration of the food product. In fact, one of the key objectives of appellants' invention is an economical fermentation product that provides statins and other soy actives in sufficient quantities which are suitable for inclusion in foods without sensory negatives. Zhang et al. offer no guidance as to how this could

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have been achieved, or suggest any alternative substrate/fungi combination that would have produced adequate levels of soy actives in an extract widely suitable for foods, or even to have recognized the problem which the appellants have solved.

Chaihorsky was relied upon by the Examiner for its teaching that "isoflavones have been isolated from soybean plants for use as dietary supplements and include isoflavones in a glucone form such as genistein and genestin" and that "typically the isoflavones are eluted by polar solvents such as methanol or ethanol". [emphasis added].

Appellants respectfully emphasize that Chaihorsky is directed to extraction and purification of chemicals directly from soy plants where ethanol is used in the purification step for 7-glycosyl-isoflavones a glycosylated isoflavone which is the real focus of the invention (see claim 1). Chaihorsky gives absolutely no guidance for an extraction solvent that should be used to extract chemicals from the fermentation products of soy beans.

Chaihorsky is even further removed from appellants invention because appellants have discovered that fermentation according to their invention, converts glycosylated isoflavones, e.g., 7-glycosyl-isoflavones, into the corresponding non-glycosylated isoflavones, which according to appellants' are more beneficial (page 11, lines 6-9). For instance, the amount of genistein and daidzein is increased in the fermented soy compared to the non-fermented soy. Surprisingly, this advantageous conversion occurs simultaneously with the production of statin. (page 11, lines 6-12).

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Thus, a person of ordinary skill in the art following the teachings of Chaihorsky would have been dissuaded from utilizing appellants fermentation extracts because 20-80% of the isoflavons are in a non-glycosylated form (page 11, line 18-19).

Manzoni et al, Zhang et al and Chaihorsky et al are directed to entirely different technical problems from applicants'. Appellants respectfully submit that absent a disclosure of the type food products, the type and derivation of the low-color (e.g., low Hue a* value, substrate at least 50% soy) health-benefit extracts recited in applicants' claims, and the significant teachings away from these elements by the prior art, the references do not present a *prima facie* case of obviousness.

Analysis of Examiners arguments

The Examiner held that one would have been motivated to choose *M. ruber* because *M. ruber* is taught by Manzoni as "successfully producing lovastatin". Appellants respectfully submit that the Examiner's assertion is incorrect. Manzoni et al teaches on page 225, left column "Only 10 of the 14 tested strains of *Monascus* produced lovastatin, in yields ranging from 1 to 20 mg/l.....Only *M paxii* AM12M strain, isolated as a spontaneous mutant, macro-morphologically different from the original *M. paxii* showed good lovastatin yield of 72 mg/l at 14 days with the whole soybean flower medium."

Appellants submit all that the artisan could have reasonably concluded from the Manzoni et al disclosure when taken as a whole is that

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- *M. ruber* produced either no lovastatin or an inferior low level of lovastatin using 3% whole soybean flower as the medium as discussed above
- *M. ruber* does not have the potential to produce provastatin in appreciable yields (Manzoni et al, page 225, right column "only m paxii AM12M produced paravastatin in appreciable yields"), and
- *M. ruber* has either no or low potential to produce monacolin J (see Manzoni et al, page 225 left column last paragraph).

The Examiner further held that one would have been motivated to use the appropriate amounts of soy ingredients because one would have been motivated during routine experiments to discover the optimal range since Manzoni et al provides the general range. (page 5 –Final Office Action).

Manzoni et al discloses a culture medium containing 3% whole or defatted soy flower. Zhang et al teaches a substrate containing over 50% rice and at most about 6.5% soy ingredients. There is no teaching or suggestion whatsoever in Manzoni et al or Zhang et al that increasing the level of soy flower and in fact using soy flower as the principle component of the culture medium would have improved the low performance of *M. ruber* in statins production, let alone a suggestion to select a culture medium comprising 50% by weight of soy ingredients selected from the group consisting of whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes to achieve acceptable color.

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The Examiner held that Zhang et al provided motivation for the formulation of a *Monascus* fermentation product in a food product (Final Rejection page 6). Appellants respectfully point out that Zhang et al teaches the fermentation product from a rice substrate, i.e., red rice, in a dietary supplement or medicament and not a food as recited in appellants' claims. As appellants have already pointed out, the fermentation products disclosed by Zhang, although acceptable for use in a dietary supplement or medicament would not have been acceptable in foods because of their intense color.

The Examiner held that it would have been obvious to include extracting the fermentation product with ethanol because one would have been motivated to do so because it is used by Chaihorsky to concentrate isoflavones from soybeans (Final Rejection page 5).

Appellants' respectfully submit that Chaihorsky when taken as a whole, would not have provided any teaching or suggestion relevant to appellants' invention because Chaihorsky deals exclusively with obtaining glycosylated isoflavones from plant extracts. The reference provides no teaching or suggestion about obtaining non-glycosylated isoflavones and statins from extracts of soy fermentation, let alone extracts that are suitable for the direct inclusion in food products.

Appellants respectfully submit that the Examiner has picked and chosen elements from Manzoni et al, Zhang et al and Chaihorsky that support an obviousness argument using appellants' disclosure as a blueprint while ignoring the key teachings of the references taken as a whole which would have in fact dissuaded a person of

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ordinary skill in the art from combining disparate elements to arrive at applicants' invention – an approach appellants submit is impermissible under 35 USC 103(a).

Regarding claims 16 and 27

Claims 16 and 27 are even more removed from the combination of Manzoni et al, Zhang et al and Chaihorsky because these claims place even tighter restrictions on the color of the fermentation extract (Hue a* value less than 10 and 0 respectively), a variable not even recognized as important in the prior art disclosures.

Regarding claims 29

Claim 29 is even more removed from the combination of Manzoni et al, Zhang et al and Chaihorsky because claim 29 specifies a particular strain of *M. ruber*, namely, F125 and F125 M1-4, that is not disclosed in the prior art references. Furthermore there is not even a remote suggestion that an alternative strain of M.ruber would be useful.

Are claim 22 and 28 unpatentable under 35 USC §103(a) over Manzoni et al (Production of Statins by filamentous Fungi, 1999), Zhang et al (US 6,046,022) Chaihorsky (US5,670,632) in further view of Zilliken (US 4, 218,489)?

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Relevant Facts

Manzoni et al, Zhang et al, Chaihorsky have already been discussed.

Zilliken discloses "Antioxidants and antioxidant compositions useful as stabilizers for food compositions, including edible fats and oils, and other compositions have been prepared and recovered from a natural source, tempeh, a fermented soybean product. An ergostadienriol which possesses antioxidative properties and which in combination with mixtures of isoflavones provides compositions having exceptional antioxidative properties has been produced." (abstract)

Zilliken teaches that the ergostadienriol is produced by fermentation of soybean with a fungus, either *Rhizopus oligosporus* or *Rhizopus oryzae*. (column 3, lines 35-36, the extraction carried out with an aqueous methanol solution (column 3, lines 42-44.

Zelliken further teaches that the subject invention also relates in one embodiment to the utilization of these compositions [erostadienriol] in the stabilization of a wide variety of food products, including edible fats and oils, such as vegetable oil, corn oil, soybean oil and lard, and other products, including cosmetics. (column 2, lines 17-20)

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Zelliken is silent regarding: fermentation of soy ingredients with *Monascus* fungus; vegetable oil extracts of such fermentation products; carrying out any type of fermentation process in the presence of vegetable oil; and the incorporation of such vegetable oil-soy fermentation extracts in foods.

In contrast appellants' claim 22 specifies that the fermentation product is formed by fermenting a substrate comprising more than 50% of soy ingredients with statins producing fungus in the presence of more than 10% of a vegetable oil.

Applicants' claim 28 specifies that the edible oil used in the extraction is vegetable oil.

Principles of Law

Same as cited above.

Appellants' arguments

Zilliken does not remedy the shortcomings discussed above of the combination of Manzoni et al, Zhang et al and Chaihorsky as a 103(a) reference against claim 19. Nor does Zelliken disclose the additional elements recited in claim 22 (fermentation in the presence of more than 10% of a vegetable oil) and claim 28 (extraction of fermentation product with edible oil). Consequently, the combination of references do not present a *prima facie* case of obviousness over appellants' claim 22 and 28.

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Analysis of Examiners arguments

In the Final Office Action Mailed November 25, 2008 (page 9) the Examiner asserted that "one of ordinary skill would have been motivated to obtain a food product comprising soy ingredients (genistein) and vegetable oil because Zilliken teach that such foods are known to have reduced oxidation and thus maintain freshness".

Appellants respectfully submit that the Examiner has again picked and chosen elements from Zelliken, in this case the words "vegetable oil", "genestein" (or isoflavones) and "food" to support an obviousness argument while ignoring appellants' invention taken as a whole and the key teachings of Zelliken taken as a whole.

Zelleken is directed to incorporating an ergostadienol which possesses antioxidative properties with mixtures of isoflavones to stabilize vegetable oils. The ergostadienol is produced by fermentation of soybean by Rhizopus oligosporus or Rhizopus oryzae and extracted with an aqueous methanol solution and purified.

In contrast applicants' food products incorporate an extract of a fermentation product formed by fermenting a substrate comprising more than 50% by weight of soy ingredients with a statin producing *Monascus ruber* fungus. The fermentation product comprises one or more statins and one or more polyphenols and has a Hue a* value less than 20. The soy ingredients are selected from the group consisting of whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes. Claim 28

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requires that the extract is an edible oil extract, i.e., that the extraction medium is edible oil, while claim 22 requires that the fermentation be carried out in the presence of more than 10% vegetable oil.

Appellants respectfully submit that there is no teaching or suggestion in Zelliken that would have rationally lead a person of ordinary skill in the art to use vegetable oil as either the extraction medium for any fermentation process or to incorporate vegetable oil at a level of more that 10% during any fermentation process.

Appellants submit that the Examiner has used appellants' invention as a road map in constructing an obvious argument based on the Zelliken disclosure which is impermissible under 103(a).

In view of the forgoing arguments, appellants submit that the claims at issue meet the 103(b) standard and are not obvious over the references cited by the Examiner. Appellants respectfully request the Board of Appeals and Interferences to reverse the rejection and have the Examiner issue the claims.

Respectfully submitted,

/ Michael P. Aronson /

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MPA/sm
201-894-2412 or 845-708-0188

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VIII. CLAIMS APPENDIX

Claim 11. Food products according to claim 19, wherein the amount of the one or more statins is 5-500 mg/kg.

Claim 12. Food product according to claim 21 wherein the amount of genistein is 20-95 wt% of the sum of the amounts of genistein and genistin.

Claim 13. Food product according to claim 21, wherein the amount of genistein is 20-80 wt.% of the sum of the amounts of genistein and genistin.

Claim 14. Food product according to claim 19, wherein the amount of statins is 5-500 mg/kg and the amount of polyphenols is 1 wt.% or higher.

Claim 15. Food product according to claim 14, wherein the amount of polyphenols is 5 wt.% or higher.

Claim 16. Food product according claim 19, wherein the fermentation product has a Hue a* value less than 10.

Claim 19. A food product selected from the group consisting of a margarine, a dressing, a sweet, a cereal bar, a breakfast cereal and a beverage, said food product comprising an extract of a fermentation product formed by fermenting a substrate comprising more than 50% by weight of soy ingredients with a statins producing

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monascus ruber fungus; wherein the fermentation product comprises one or more statins and one or more polyphenols and has a Hue a* value less than 20; wherein said soy ingredients are selected from the group consisting of whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes; and wherein said extract is an ethanol extract or an edible oil extract.

Claim 20. A food product according to claim 19 wherein the substrate comprises more than 80% soy ingredients.

Claim 21. A food product according to claim 19 wherein the polyphenols comprise genistein and genistin, and wherein the amount of genistein is 10-99 wt.% of the sum of the amounts of genistein and genistin.

Claim 22. A food product according to claim 19 wherein the fermentation product is formed by fermenting a substrate comprising more than 50% of soy ingredients with statins producing fungus in the presence of more than 10% of a vegetable oil.

Claim 23. A food product according to claim 19 wherein the fermentation product further comprises an amount of one or more compounds selected from the group consisting of polyunsaturated fatty acids, phytosterols, proteins, peptides, dietary fibers, and saponins.

Claim 24. A food product according to claim 19 wherein the substrate comprises whole soybeans or crushed whole soybeans.

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Claim 27. A food product according to claim 19 wherein the Hue a^* value is less than 0.

Claim 28. A food product according to claim 19 wherein the edible oil is a vegetable oil.

Claim 29. A food product according to claim 19 wherein the monascus ruber fungus is monascus ruber strain F125 or monascus ruber strain F125 M1-4.

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IX. EVIDENCE APPENDIX

None.

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None.